

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ROME DIVISION**

HENRY LEE BROWN,

Plaintiff,

v.

JOHNSON & JOHNSON and  
ETHICON, INC.,

Defendants.

Civil Action No. 4:17-cv-00036-HLM

JURY TRIAL DEMANDED

**ANSWER AND DEFENSES OF DEFENDANT  
ETHICON, INC. TO PLAINTIFF’S COMPLAINT**

Defendant Ethicon, Inc. (“Ethicon”), by and through its attorneys, responds to Plaintiff’s Complaint (“Complaint”) as follows.

**RESPONSE TO “PARTIES”<sup>1</sup>**

1. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 1 of Plaintiff’s Complaint, and, therefore, denies those allegations.

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<sup>1</sup> The repetition of the Complaint’s subheadings is done solely for organizational purposes and is not an admission as to their truth.

2. Ethicon admits only that Johnson & Johnson is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Ethicon denies the remaining allegations contained in Paragraph 2 of Plaintiff's Complaint.

3. Ethicon admits only that Johnson & Johnson is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson does not design, manufacture, market, package, label or sell any product. Ethicon denies the remaining allegations contained in Paragraph 3 of Plaintiff's Complaint.

4. Ethicon admits that it is a New Jersey corporation with its principal place of business in Somerville, New Jersey, and it is a subsidiary of Johnson & Johnson. Ethicon admits that its products are available for purchase in Georgia and that its registered agent in Georgia is Corporation Process Company, 2180 Satellite Blvd., Duluth, GA 30097. Ethicon denies the remaining allegations contained in Paragraph 4 of Plaintiff's Complaint.

5. Ethicon admits that it has researched, developed, tested, manufactured, produced, marketed, promoted and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not research, develop, test, manufacture, produce, market, promote or sell any product. Ethicon

denies the remaining allegations contained in Paragraph 5 of Plaintiff's Complaint.

6. Ethicon admits only that it has researched, developed, tested, manufactured, produced, marketed, promoted, distributed and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not research, develop, test, manufacture, produce, market, promote, distribute or sell any product. Ethicon denies the remaining allegations contained in Paragraph 6 of Plaintiff's Complaint.

7. Ethicon denies the allegations contained in Paragraph 7 of Plaintiff's Complaint.

8. Ethicon denies the allegations contained in Paragraph 8 of Plaintiff's Complaint.

**RESPONSE TO "JURISDICTION AND VENUE"**

9. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 9 of Plaintiff's Complaint, and, therefore, denies those factual allegations and legal conclusions.

10. Ethicon denies the allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. Ethicon admits that it is authorized to transact business in Georgia under the registered entity name of Ethicon, Inc. Ethicon further admits that its registered agent in Georgia is Corporation Process Company, 2180 Satellite Blvd., Duluth, GA 30097. Ethicon denies the remaining allegations contained in Paragraph 11 of Plaintiff's Complaint.

12. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 12 of Plaintiff's Complaint, and, therefore, denies those factual allegations and legal conclusions.

**RESPONSE TO "FACTS COMMON TO ALL COUNTS"**

13. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 13 of Plaintiff's Complaint.

14. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon admits only that it has manufactured, sold and distributed Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not manufacture, sell or distribute any product. Ethicon denies the remaining allegations contained in Paragraph 14 of Plaintiff's Complaint.

15. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 15 of Plaintiff's Complaint.

16. Ethicon admits only that it has researched, designed, developed, tested, manufactured, produced, marketed, promoted, distributed and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not research, design, develop, test, manufacture, produce, market, promote distribute or sell any product. Ethicon denies the remaining allegations contained in Paragraph 16 of Plaintiff's Complaint.

17. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon admits only that it has designed, manufactured and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not design, manufacture or sell any product. Ethicon denies the remaining allegations contained in Paragraph 17 of Plaintiff's Complaint.

18. Ethicon admits only that its Physiomesh is safe and effective for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 18 of Plaintiff's Complaint.

19. Ethicon denies the allegations contained in Paragraph 19 of Plaintiff's Complaint.

20. Ethicon denies the allegations contained in Paragraph 20 of Plaintiff's Complaint.

21. Ethicon denies the allegations contained in Paragraph 21 of Plaintiff's Complaint.

22. Ethicon denies the allegations contained in Paragraph 22 of Plaintiff's Complaint.

23. Ethicon denies the allegations contained in Paragraph 23 of Plaintiff's Complaint.

24. Ethicon denies the allegations contained in Paragraph 24 of Plaintiff's Complaint.

25. Ethicon denies the allegations contained in Paragraph 25 of Plaintiff's Complaint.

26. Ethicon denies the allegations contained in Paragraph 26 of Plaintiff's Complaint.

27. Ethicon denies the allegations contained in Paragraph 27 of Plaintiff's Complaint.

28. Ethicon denies the allegations contained in Paragraph 28 of Plaintiff's Complaint.

29. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 29 of Plaintiff's Complaint.

30. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 30 of Plaintiff's Complaint.

**RESPONSE TO "COUNT I  
STRICT PRODUCT LIABILITY: DEFECTIVE DESIGN"**

31. Ethicon incorporates by reference its responses to the allegations contained in Paragraphs 13 through 30 of Plaintiff's Complaint.

32. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 32 of Plaintiff's Complaint.

33. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that

allegation. Ethicon denies the remaining allegations contained in Paragraph 33 of Plaintiff's Complaint.

34. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon admits only that it has designed, manufactured and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not design, manufacture or sell any product. Ethicon denies the remaining allegations contained in Paragraph 34 of Plaintiff's Complaint.

35. Ethicon denies the allegations contained in Paragraph 35 of Plaintiff's Complaint.

36. Ethicon denies the allegations contained in Paragraph 36 of Plaintiff's Complaint.

37. Ethicon denies the allegations contained in Paragraph 37 of Plaintiff's Complaint.

38. Ethicon denies the allegations contained in Paragraph 38 of Plaintiff's Complaint.

39. Ethicon denies the allegations contained in Paragraph 39 of Plaintiff's Complaint.



40. Ethicon denies the allegations contained in Paragraph 40 of Plaintiff's Complaint.

41. Ethicon denies the allegations contained in Paragraph 41 of Plaintiff's Complaint.

42. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 42 of Plaintiff's Complaint

43. Ethicon denies the allegations contained in Paragraph 43 of Plaintiff's Complaint.

44. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 44 of Plaintiff's Complaint.

45. Ethicon denies the allegations contained in Paragraph 45 of Plaintiff's Complaint.

**RESPONSE TO "COUNT II  
STRICT PRODUCT LIABILITY: FAILURE TO WARN"**

46. Ethicon incorporates by reference its responses to the allegations contained in Paragraphs 13 through 30 of Plaintiff's Complaint.

47. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 47 of Plaintiff's Complaint.

48. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 48 of Plaintiff's Complaint.

49. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 49 of Plaintiff's Complaint.

50. Ethicon denies the allegations contained in Paragraph 50 of Plaintiff's Complaint.

51. Ethicon denies the allegations contained in Paragraph 51 of Plaintiff's Complaint.

52. Ethicon denies the allegations contained in Paragraph 52 of Plaintiff's Complaint.

53. Ethicon denies the allegations contained in Paragraph 53 of Plaintiff's Complaint.

54. Ethicon denies the allegations contained in Paragraph 54 of Plaintiff's Complaint.

55. Ethicon denies the allegations contained in Paragraph 55 of Plaintiff's Complaint.

56. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Henry Lee Brown used any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 56 of Plaintiff's Complaint.

57. Ethicon denies the allegations contained in Paragraph 57 of Plaintiff's Complaint.

**RESPONSE TO "COUNT III  
NEGLIGENCE"**

58. Ethicon incorporates by reference its responses to the allegations contained in Paragraphs 13 through 57 of Plaintiff's Complaint.

59. Ethicon admits only that it has certain duties imposed on it by law, but denies that it breached any duty. Ethicon denies the remaining allegations contained in Paragraph 59 of Plaintiff's Complaint.

60. Ethicon denies the allegations contained in Paragraph 60 of Plaintiff's Complaint.

61. Ethicon denies the allegations contained in Paragraph 61 of Plaintiff's Complaint.

**RESPONSE TO "COUNT IV  
PUNITIVE DAMAGES"**

62. Ethicon incorporates by reference its responses to the allegations contained in Paragraphs 13 through 61 of Plaintiff's Complaint.

63. Ethicon denies the allegations contained in Paragraph 63 of Plaintiff's Complaint.

**RESPONSE TO "PRAYER FOR RELIEF"**

Ethicon denies the allegations contained in the "WHEREFORE" Paragraph under "Prayer for Relief," including subparts, (A) – (E), of Plaintiff's Complaint, and denies that Plaintiff is entitled to any judgment, any recovery, or any form of relief whatsoever from Ethicon.

Ethicon denies any and all allegations contained in Plaintiff's Complaint not specifically admitted hereinabove.

## **AFFIRMATIVE DEFENSES**

### **FIRST DEFENSE**

The Complaint fails to state a cause of action upon which relief can be granted.

### **SECOND DEFENSE**

The Complaint fails to state a cause of action upon which relief can be granted due to lack of adequate product identification.

### **THIRD DEFENSE**

Plaintiff's claims are barred for lack of subject matter jurisdiction.

### **FOURTH DEFENSE**

Plaintiff's claims are barred for lack of personal jurisdiction.

### **FIFTH DEFENSE**

Venue in this Court is improper, and this matter should be dismissed on intra-state or interstate forum *non conveniens* grounds.

### **SIXTH DEFENSE**

Certain of Plaintiff's claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

### **SEVENTH DEFENSE**

Plaintiff may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter. Ethicon will undertake

sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **EIGHTH DEFENSE**

Ethicon is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from the laws of the State of Georgia and any other state whose law is deemed to apply in this case.

#### **NINTH DEFENSE**

Plaintiff's request for attorneys' fees is improper and barred by applicable law, including O.C.G.A. § 13-6-11 and § 9-15-14.

#### **TENTH DEFENSE**

Plaintiff's claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the product at issue is regulated by the U.S. Food and Drug Administration ("FDA") under the Medical Device Amendments, 21 U.S.C. § 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations.

### **ELEVENTH DEFENSE**

At all relevant times, Ethicon was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations, and Plaintiff's claims are accordingly barred.

### **TWELFTH DEFENSE**

Plaintiff's claims against Ethicon are expressly and/or impliedly preempted by federal law, including but not limited to, the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. § 301 *et seq.*; *see also* Fed. Reg. 3922 (Jan. 24, 2006).

### **THIRTEENTH DEFENSE**

Plaintiff's claims are barred because Ethicon complied with all applicable state and federal statutes regarding the product at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that Plaintiff's claims are not barred, Ethicon is entitled to a presumption that the product at issue is free from any defect or defective condition as the plans or design for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were

in conformity with government standards established for the industry that were in existence at the time the plans or designs for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were adopted.

#### **FOURTEENTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations promulgated there under.

#### **FIFTEENTH DEFENSE**

Plaintiff's claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Ethicon complied with all applicable statutes and with the requirements and regulations of the FDA. *Inam Int'l, Inc. v. Broan-Nutone LLC*, 2007 U.S. Dist. LEXIS 96028, at \*40-42 (N.D. Ga., Sep. 21, 2007) (citing to the Restatement (Third) of Torts – Products Liability (1998), Section 2's provisions regarding foreseeability analysis).



### **SIXTEENTH DEFENSE**

Any claims by Plaintiff relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Ethicon to petition the government.

### **SEVENTEENTH DEFENSE**

Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for medical devices.

### **EIGHTEENTH DEFENSE**

Plaintiff cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by Plaintiff is subject to the exclusive regulation of FDA.

### **NINETEENTH DEFENSE**

Plaintiff's claims are barred in whole or in part by Plaintiff's failure to assert a safer design for the product at issue.

### **TWENTIETH DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue provided a benefit to users of such products and greatly outweighed any risk created by using such product, any risk could not have been avoided through the

use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

#### **TWENTY-FIRST DEFENSE**

Plaintiff's claims are barred because the utility of the product at issue outweighed its risks.

#### **TWENTY-SECOND DEFENSE**

Plaintiff's claims are barred, in whole or in part, because Ethicon made no false, material or knowing misrepresentations to Plaintiff, nor did Ethicon conceal or omit any material information from Plaintiff.

#### **TWENTY-THIRD DEFENSE**

To the extent Plaintiff claims misrepresentation and/or fraud, such claims must be dismissed because Plaintiff failed to plead such claims with the requisite particularity as required by Fed. R. Civ. P. 9(b).

#### **TWENTY-FOURTH DEFENSE**

The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Ethicon given the state of scientific knowledge and state-of-the-art at the time of the alleged injuries. At all times relevant, the product at issue conformed to state-of-the-art specifications and state-of-scientific knowledge

for such product at that time, as well as all applicable statutes and regulations, including those of FDA.

#### **TWENTY-FIFTH DEFENSE**

Plaintiff knowingly and voluntarily assumed any and all risks associated with the use of the product at issue in this case and thus the “last clear chance” and assumption of the risk doctrines bar in whole or in part the damages that Plaintiff seeks to recover herein. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff’s claims are established.

#### **TWENTY-SIXTH DEFENSE**

Plaintiff’s claims are barred, in whole or in part, because Ethicon acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its product.

#### **TWENTY-SEVENTH DEFENSE**

At all relevant times herein, the product in question was manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

### **TWENTY-EIGHTH DEFENSE**

Plaintiff's inadequate warning claims are barred because the alleged risk of which Plaintiff claims is open, obvious, and/or a matter of common knowledge.

### **TWENTY-NINTH DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue was consistent with and/or exceeded consumer expectations.

### **THIRTIETH DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue was at all times properly prepared, packaged, and distributed, and was not defective or unreasonably dangerous.

### **THIRTY-FIRST DEFENSE**

Adequate and complete warnings and instructions were provided with the product at issue. The product at issue was neither defective nor unreasonably dangerous when used according to its Instructions for Use.

### **THIRTY-SECOND DEFENSE**

At all relevant times, the warnings and instructions accompanying the product at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the product were presumptively adequate.

### **THIRTY-THIRD DEFENSE**

Plaintiff's causes of action are barred by the learned intermediary doctrine.

### **THIRTY-FOURTH DEFENSE**

Ethicon is not liable to Plaintiff because the end users of the product at issue, Plaintiff Henry Lee Brown's physician(s), were sophisticated users of the product.

### **THIRTY-FIFTH DEFENSE**

Ethicon states that the sole proximate cause of the injuries and/or damages alleged by Plaintiff was the actions, omissions, or negligence of a person or persons, other than Ethicon, for whose actions, omissions, or negligence Ethicon is in no way liable. Plaintiff is not, therefore, entitled to recover from Ethicon in this action. As to Plaintiff or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of Plaintiff, if any, Ethicon expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of Georgia and any other applicable state.

### **THIRTY-SIXTH DEFENSE**

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by Plaintiff's own fault, which bars or proportionately reduces Ethicon's liability, if any, for Plaintiff's alleged damages.

### **THIRTY-SEVENTH DEFENSE**

Plaintiff voluntarily and unreasonably chose to encounter known dangers.

### **THIRTY-EIGHTH DEFENSE**

The liability of Ethicon, if any, for Plaintiff's non-economic loss must be apportioned in accordance with the provisions of the law of Georgia, including O.C.G.A. § 51-12-33, and any other state whose law is deemed to apply in this case.

### **THIRTY-NINTH DEFENSE**

In the event Ethicon is held liable to Plaintiff, which liability is expressly denied, and any other co-defendants are also held liable, Ethicon is entitled to a percentage contribution of the total liability from said co-defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of any applicable state.

#### **FORTIETH DEFENSE**

There is no causal relationship between Ethicon's conduct and the injuries and damages alleged by Plaintiff in the Complaint.

#### **FORTY-FIRST DEFENSE**

At all times mentioned herein, Plaintiff Henry Lee Brown was negligent, careless and at fault and conducted himself so as to contribute substantially to his alleged injuries, losses, and damages. Said negligence, carelessness and fault of Plaintiff bars in whole or in part the damages which Plaintiff seeks to recover as provided by O.C.G.A. § 51-12-33(a) and (g) and any other applicable law. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **FORTY-SECOND DEFENSE**

Plaintiff's alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said product. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid

waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **FORTY-THIRD DEFENSE**

Plaintiff's alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

#### **FORTY-FOURTH DEFENSE**

Plaintiff's alleged injuries, losses, or damages attributable to the product at issue in this case, if any, were caused by the acts or omissions of third parties for which Ethicon has no legal responsibility. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **FORTY-FIFTH DEFENSE**

Ethicon expressly denies any third party engaging in the acts alleged by Plaintiff was acting as Ethicon's agent or servant, at the instruction of Ethicon, or within its control. Therefore, Plaintiff's claims, to the extent they seek to recover



for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

#### **FORTY-SIXTH DEFENSE**

Plaintiff's causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Ethicon.

#### **FORTY-SEVENTH DEFENSE**

Plaintiff's claims are or may be barred by his failure to comply with conditions precedent to his right to recover. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **FORTY-EIGHTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, by the doctrine of avoidable consequences. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being

estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **FORTY-NINTH DEFENSE**

The claims of Plaintiff may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to properly preserve evidence necessary to the determination of the claims. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **FIFTIETH DEFENSE**

Plaintiff's claims against Ethicon are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if Plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of Plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than Plaintiff, or, if not disclosed by Plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

#### **FIFTY-FIRST DEFENSE**

Some or all of Plaintiff's claims are, or may be, barred by the statutes of limitations, prescription, and/or statutes of repose of Georgia or any other applicable state. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **FIFTY-SECOND DEFENSE**

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

#### **FIFTY-THIRD DEFENSE**

Plaintiff's alleged damages, if any, are barred in whole or in part by Plaintiff's failure to mitigate such damages. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **FIFTY-FOURTH DEFENSE**

The sale, labeling and marketing of the product at issue in this litigation is not, and was not, likely to mislead or deceive the public.

#### **FIFTY-FIFTH DEFENSE**

The product at issue was altered after the product left the control, custody and possession of Ethicon, and said alteration relieves Ethicon of any and all liability. Ethicon will undertake sufficient discovery to determine the full extent of this defense, and this defense is set forth to avoid waiving or being estopped to raise and rely on such defense once the facts underlying Plaintiff's claims are established.

#### **FIFTY-SIXTH DEFENSE**

The product at issue in this litigation is not defective or unreasonably dangerous because it is a prescription medical device bearing adequate warnings, and is subject to the comment j exception to strict tort liability as set forth in Section 402A of the Restatement (Second) of Torts (1965), or because it is a prescription medical device that is unavoidably unsafe pursuant to comment k of Section 402A of the Restatement (Second) of Torts (1965).

#### **FIFTY-SEVENTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, to the extent Plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised his claims by any means.

#### **FIFTY-EIGHTH DEFENSE**

To the extent allowable under applicable state law, any recovery by Plaintiff must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

#### **FIFTY-NINTH DEFENSE**

The Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

#### **SIXTIETH DEFENSE**

Ethicon specifically pleads as to Plaintiff's strict liability claims, all affirmative defenses available to Ethicon under the rules and statutes of Georgia and any state whose law is deemed to apply in this case, and under any common law principles of Georgia and any state whose law is deemed to apply in this case.

#### **SIXTY-FIRST DEFENSE**

Ethicon specifically pleads as to Plaintiff's negligence claims all affirmative defenses available to Ethicon under the rules and statutes of Georgia and any state whose law is deemed to apply in this case, and under any common law principles of Georgia and any state whose law is deemed to apply in this case.

### **SIXTY-SECOND DEFENSE**

The Complaint fails to state facts sufficient to entitle Plaintiff to an award of punitive damages.

### **SIXTY-THIRD DEFENSE**

Plaintiff's claim for punitive damages is barred because the product at issue was manufactured and labeled in accordance with the terms of FDA's clearance of the product at issue.

### **SIXTY-FOURTH DEFENSE**

No act or omission of Ethicon was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

### **SIXTY-FIFTH DEFENSE**

Plaintiff's claims for pain and suffering are barred because they violate Ethicon's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and Georgia.

### **SIXTY-SIXTH DEFENSE**

The imposition of punitive or exemplary damages would violate Ethicon's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions,

common law, public policy, applicable statutes and court rules of Georgia and any other applicable state to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. To the extent that punitive damages awarded to Plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent *de novo* review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended, the Georgia Constitution, or any other applicable state's constitution as amended; (3) imposed

where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Ethicon's conduct within the state where Plaintiff resides, or in any other way subjecting Ethicon to impermissible multiple punishment for the same alleged wrong.

#### **SIXTY-SEVENTH DEFENSE**

Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of Georgia and any other applicable state under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

#### **SIXTY-EIGHTH DEFENSE**

Ethicon is entitled to the protection afforded it under O.C.G.A. § 51-12-5, *et seq.* and any award of punitive damages to Plaintiff in this case would be in violation of the limitations set forth in O.C.G.A. § 51-12-5.1.

#### **SIXTY-NINTH DEFENSE**

With respect to Plaintiff's demand for punitive damages, Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW*



*of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under Georgia law and any other state's law.

#### **SEVENTIETH DEFENSE**

Ethicon asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of Georgia and any other applicable state.

#### **SEVENTY-FIRST DEFENSE**

Ethicon specifically pleads as to Plaintiff's claims for punitive damages, all affirmative defenses available to Ethicon under the rules and statutes of Georgia and any state whose law is deemed to apply in this case, and under any common law principles of Georgia and any state whose law is deemed to apply in this case.

#### **SEVENTY-SECOND DEFENSE**

Ethicon hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

### **SEVENTY-THIRD DEFENSE**

Ethicon reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

### **DEMAND FOR JURY TRIAL**

Ethicon specifically requests and demands a trial by jury of 12 as to issues so triable.

WHEREFORE, Defendant Ethicon prays that:

- (1) Plaintiff takes nothing by reason of his Complaint;
- (2) The Complaint be dismissed in its entirety and that a Judgment against Plaintiff and in favor of Ethicon be entered;
- (3) Ethicon be awarded its costs and expenses; and
- (4) This Court award Ethicon any other general or specific relief as this Court may deem just and proper.

Respectfully submitted this 24th day of March, 2017.

TROUTMAN SANDERS LLP

/s/ David F. Norden

N. KAREN DEMING

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DAVID F. NORDEN

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***ATTORNEYS FOR DEFENDANT  
ETHICON, INC.***

### **FONT CERTIFICATION**

Pursuant to Local Rule 7.1 D, I hereby certify that the foregoing document was prepared using Times New Roman 14 point type as provided in Local Rule 5.1.

/s/ David F. Norden  
DAVID F. NORDEN  
Georgia Bar No. 545647

**CERTIFICATE OF SERVICE**

I hereby certify that on the 24th day of March, 2017, I electronically filed the foregoing **ANSWER AND DEFENSES OF DEFENDANT ETHICON, INC. TO PLAINTIFF'S COMPLAINT** with the Clerk of Court using the CM/ECF system and served Plaintiff's counsel with a copy of same via U.S. Mail with adequate first class postage affixed thereto and addressed as follows:

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This 24th day of March, 2017.

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